

Primovate

Clobetasol Propionate USP 0.05%

Composition

Primovate Cream: Each gram cream contains Clobetasol Propionate USP 0.5 mg.

Primovate Ointment: Each gram ointment contains Clobetasol Propionate USP 0.5 mg.

Pharmacology

Clobetasol Propionate is a highly potent topical steroid. It has both local anti-inflammatory and immunosuppressive activity. Clobetasol, as the Propionate salt, is only used topically on the skin and its effects are limited to the local anti-inflammatory activity. When given systemically it has standard glucocorticoid activity and binds with high affinity to the glucocorticoid receptor. Clobetasol Propionate inhibits the adherence of neutrophils and monocyte-macrophages; to the capillary endothelial cells of inflamed area. Clobetasol blocks the effect of macrophage migration inhibitory factor and decreases the activation of plasminogen to plasmin.

Indication

Primovate cream & ointment is indicated for the topical therapy of recalcitrant corticosteroid responsive dermatoses, including severe cases of psoriasis (excluding widespread plaque psoriasis) and eczematous dermatitis. Primovate ointment is generally chosen for dry, lichenified or scaly lesions or where a more occlusive effect is required. Primovate cream is suitable for moist or weeping lesions.

Dosage And Administration

Primovate cream and ointment are applied sparingly to cover the affected area, and gently rubbed into the skin. Frequency of application is two to three times daily according to the severity of the condition. The total dose of Primovate cream and ointment applied should not exceed 50 grams weekly. Therapy should be discontinued if no response is noted after a week or as soon as the lesion heals. It is advisable to use Primovate cream and ointment for brief periods only.

Contraindications:

Clobetasol Propionate cream & ointment is contraindicated in patients with hypersensitivity to Clobetasol Propionate. This preparation is contraindicated also in the treatment of primary infected bacterial or fungal skin lesions if no anti-infective agent is used simultaneously, in primary cutaneous viral infections (i.e., herpes simplex, vaccinia and varicella) and in tuberculous skin lesions. Clobetasol Propionate is also contraindicated in dermatoses in children under one year of age, including dermatitis and diaper eruptions.

Warnings & precautions:

Clobetasol Propionate should be used with caution on

lesions close to the eye. When Clobetasol Propionate is used over extensive areas for prolonged periods, it is possible that sufficient absorption may take place to give rise to adrenal suppression. This is particularly true for pediatric patients who may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratio. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis, careful patient supervision is important. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

Side effects:

As with other topical corticosteroids, prolonged use of large amounts of Clobetasol Propionate or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercortisolism. This effect is more likely to occur in infants and children, and if occlusive dressings are used. Local atrophy may occur after prolonged treatment. In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the diseases. Clobetasol Propionate is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately.

Use in pregnancy and lactation

Clobetasol Propionate should be avoided in pregnant women. Mothers using large amounts of the drug should be aware of potential excretion in milk.

Storage

Store below 30°C in a dry place, away from light. Keep out of reach of children.

Packaging

Primovate cream: Each pack has a laminated tube containing 20gm cream

Primovate ointment: Each pack has a laminated tube containing 20gm ointment

Manufactured By

BEACON[®]
Pharmaceuticals PLC

Bhaluka, Mymensingh, Bangladesh